

### Version With Markings To Show Changes Made

The title has been rewritten as follows.

--Packaged Condoms--

#### In the Specification

New pages have been submitted to replace those on file with blank spaces.

#### In the Claims

--1. (amended) ~~An universal~~ A package containing a condom and an antiviral composition, which comprises:

a) an effective amount of a microbicidal agent to prevent sexually transmitted diseases;

b) an acidic buffer in an effective amount for maintaining the composition at a pH not greater than 5 for the site of administration; and

c) an effective amount of wound healing and diffusion impedance compound which is a member selected from the group consisting of dextran sulfate, chondroitin sulfate, pentosan polysulfate, glucosamine glycan, sulfated and sulfonated polymers and a hyaluronate.

2. (amended) The ~~composition~~ package of claim 1 wherein said hyaluronate is hyaluronic acid.

3. (amended) The ~~composition~~ package of claim 1 wherein said microbicidal agent is selected from the group consisting of nonoxynol-9, octoxynol-9, acyclovir, benzalkonium chloride, and aprotinin.

4. (amended) The ~~composition~~ package of claim 1 wherein said microbicidal agent is also spermicidal.

5. (amended) The ~~composition~~ package of claim 1 including an acrylic acid polymer.

6. (amended) The ~~composition~~ package of claims 1 including lubricants.

7. (amended) The ~~composition~~ package of claim 1 including about 0.1 to 10% by weight of detergent.

8. (amended) The ~~composition~~ package of claim 1 wherein said composition is for use in a non-mucosal area and includes a cellulosic binder.

9. (amended) The ~~composition package~~ of claim 1 ~~in a gel~~ wherein antiviral composition is in the form of a gel.

10. (amended) The ~~composition package~~ of claim 9 wherein said ~~lubricant base is a member selected from the group consisting of~~ gel comprises water, polyethylene glycol, propylene glycol, glycerin, and a silicone.

11. (amended) A ~~composition package~~ containing a condom and a spermicidal and microbicial composition comprising:

- a) about 0.1 to 10% by weight of a spermicidal and microbicial detergent;
  - b) about 0.5 to 5% by weight of a buffering agent;
  - c) about 0.1 to 5% by weight of ~~a member selected from the group consisting of dextran sulfate, chondroitin sulfate, pentosan polysulfate and a hyaluronate~~ hyaluronic acid,
- said composition having a pH less than 5 and in the form of a lotion, crème or a gel.

12. (amended) The ~~composition package~~ of claim 11 comprising:

- a) about 0.1 to 10% by weight of nonoxynol-9;
- b) about 0.5 to 5% by weight of polyacrylic acid; and
- c) about 0.1 to 5% of hyaluronic acid, said composition including a lubricating base and having a pH of about 5.

The preferred lubricants include water, propylene glycol, glycerin, polyethylene glycol and a silicone.

Thickeners of up to 50% by weight of the lubricant base can be utilized. Suitable thickeners include cellulosic polymers, natural gums, synthetic polymers and silicon dioxide.

The preferred cellulosic thickeners, which are used in an amount up to about 3% by weight include methylcellulose, carboxymethylcellulose, hydroxypropylcellulose, hyaluronic acid, sulfonated and sulfonated polysaccharides.

The preferred natural gums, which can be used in amounts up to about 5% by weight include xantham gum, aliginates and gelatin.

A<sup>2</sup> The preferred synthetic polymers, which can be used include Carbopol®, polyacrylic acid, polymethacrylic acid, hydroxyethyl methacrylate, polyacrylamide, polyvinyl pyrrolidone and polyvinyl alcohol.

The following examples illustrating the compositions of the invention are not intended to limit the scope of the invention. The amounts indicated are by weight percent unless otherwise noted.

#### Example 1

A gel is prepared by admixing the following ingredients:

<u>Ingredient</u>	<u>Wt. %</u>
1. Propylene Glycol	43.44
2. Carbopol	2.10
3. Dipropylene glycol	10.00
4. Xantham Gum	0.15

5.	Ethoxydiglycol	15.00
6.	Dimethylisosorbide	10.00
7.	Ascorbic Acid	2.00
8.	Chloroxylonol	0.20
9.	Linoleamidopropyl PG-diammonium chloride phosphate	1.50
10.	Glycereth 4,5 Lactate	2.00
11.	Aloe Vera Gel	2.00
12.	Aprotinin	2.00
13.	Benzalkonium chloride	0.50
14.	Hyaluronic acid	8.00
15.	Cocamidopropyl PG-diammonium chloride phosphate	1.00

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 Ingredients 1 and 2 are mixed to disperse and form a gel. About 80% of ingredient 3 is mixed with ingredient 4, added to the gel and slightly heated with admixture. The balance of 3 is mixed with ingredients 5-10 and added to the gel. Ingredients 11-15 are then admixed then added to the gel at 38 degrees C. After mixing, the pH is adjusted to about 4 and then the gel is brought to room temperature. The composition can be used for packaging condoms.

#### Example 2

A topical lotion is prepared by admixing the following ingredients:

<u>Ingredient</u>	<u>Wt %</u>
Propylene Glycol Stearate	9.50
Isocetyl alcohol	5.00

PEG-100 Stearate	1.20
Hyaluronic acid	2.00
Methyl paraben	0.20
Propylene glycol	13.10
Sorbitan palmitate	0.60
Octoxynol-9	6.00
Mate extract	0.50
Water	<u>q.s.</u>
	100%

### Example 3

A gel is prepared by admixing the following ingredients.

<u>Ingredient</u>	<u>Wt %</u>
Carbopol 940	4.10
Xanthan Gum	0.15
Propylene glycol	47.94
Dipropylene glycol	10.00
Ethoxydiglycol	15.00
Dimethylisosorbide	10.00
Hyaluronic acid	8.00
Nonoxynol-9	0.05
Aprotinin	3.76
Buffer	<u>2.00</u>
	100%

The pH of the gel is about 4. The gel can be used in packaging condoms.

#### Example 4

An antimicrobial lubricant is prepared as follows:

A. Lubricant Base

<u>Ingredient</u>	<u>% w/w</u>
Propylene glycol	80
Carragenen gum	3
Lubrajel®	<u>17</u>
	100%

B. Preparation of Composition

To the admixture of the lubricant base from Part A is added 5% by weight hyaluronic acid, 3% by weight of nonoxynol-9 and 3% by weight of polyacrylic acid. The mixture is then brought to a pH of 4. If desired, 0.5% of zinc acetate or mate extract may added.

The composition can be used in combination with condoms which are to be packaged.

#### Example 5

A lubricating composition having anti-microbial and spermicidal activity is prepared by mixing the following ingredients:

<u>Ingredient</u>	<u>% w/w</u>
Hyaluronic acid	5.0
Octoxynol-9	0.5
Zinc gluconate	0.5
Acyclovir	0.5
Carragenen gum	3.0
Carbopol	40.0
Water	<u>g.s.</u>
	100%

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The composition can be used as in connection with packaged condoms or in combination with other ingredients to form an antimicrobial lotion.

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What Is Claimed Is:

1. An universal antiviral composition, which comprises:
  - a) an effective amount of a microbicidal agent to prevent sexually transmitted diseases;
  - b) an acidic buffer in an effective amount for maintaining the composition at a pH not greater than 5 for the site of administration; and
  - c) an effective amount of wound healing and diffusion impedance compound which is a member selected from the group consisting of dextran sulfate, chondroitin sulfate, pentosan polysulfate, glucosamine glycan, sulfated and sulfonated polymers and a hyaluronate.
2. The composition of claim 1 wherein said hyaluronate is hyaluronic acid.
3. The composition of claim 1 wherein said microbicidal agent is selected from the group consisting of nonoxynol-9, octoxynol-9, acyclovir, benzalkonium chloride and aprotinin.
4. The composition of claim 1 wherein said microbicidal agent is spermicidal.
5. The composition of claim 1 including an acrylic acid polymer.
6. The composition of claim 1 including lubricants.
7. The composition of claim 1 including about 0.1 to 10% by weight of detergent.
8. The composition of claim 1 wherein said composition is for use in a non-mucosal area and includes a cellulosic binder.
9. The composition of claim 1 in a gel.